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4 UNITED STATES DISTRICT COURT
5 SOUTHERN DISTRICT OF CALIFORNIA
6 IN RE INCRETIN-BASED THERAPIES Case No. 3:13-md-02452-AJB-MDD
7 PRODUCTS LIABILITY LITIGATION MDL 2452

8 Hon. Mitchell D. Dembin

9 *This Document Relates to All Cases*

10 **JOINT MOTION FOR DETERMINATION OF PROCEDURES FOR**
11 **PRODUCTION OF ELECTRONICALLY STORED INFORMATION**
12 **PROTOCOL DISPUTES**

13 Pursuant to the Court's November 19, 2013 Order Regarding Discovery
14 Disputes Identified in Joint Submission Filed November 18, 2013 (Doc. No. 192),
15 undersigned counsel for the plaintiffs, together with undersigned counsel for
16 defendants Amylin Pharmaceuticals, LLC ("Amylin") and Eli Lilly and Company
17 ("Lilly") (collectively, the "Parties") ask the Court to address certain questions
18 concerning proposed ESI protocols.

19 **STATEMENT OF AREAS OF DISPUTE**

20 Plaintiffs' proposals are attached hereto as Exhibits 1 and 2. Amylin and
21 Lilly's proposals are attached hereto as Exhibits 3 and 4. Plaintiffs and Defendants
22 currently have a dispute regarding section A and sections B.1, 2, and 4.
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1 **I. THE PLAINTIFFS' POSITION**

2 Defendants are seeking to avoid their discovery obligations under the Federal
3 Rules of Civil Procedure. Defendants have stated in writing that they will not be
4 fully complying with the PSC's valid discovery requests in this MDL because
5 several years ago they produced documents to different plaintiffs' attorneys, in a
6 different jurisdiction, in cases alleging their products cause a different injury, i.e.,
7 pancreatitis. Rather than even consider responding to Plaintiffs' actual requests,
8 Defendants re-printed those documents — which were allegedly responsive to
9 unspecified discovery requests — and tendered them to the PSC. Now, in the
10 context of a proposed order governing the production of electronically stored
11 information, ("ESI" order), they seek a *sub silentio* protective order precluding
12 Plaintiffs from ordinary ESI discovery. Instead, Defendants demand Plaintiffs
13 review the old production from a prior lawsuit and "should plaintiffs believe that
14 any prior search was insufficient...plaintiffs will notify [defendants] of the asserted
15 deficiency and their basis for believing it material..." See Exhibit 3 at C.2 and
16 Exhibit 4 at C.

17 Rather than producing documents in response to specific discovery requests
18 in this MDL, Defendants are asking the Plaintiffs to identify which documents
19 Defendants did *not* produce in prior litigation that could be responsive to Plaintiffs'
20 requests. It is impossible for Plaintiffs to know what Defendants have *not* produced
21 that *might* be responsive; that information is solely within the knowledge of the
22 defendants. This improperly puts on the Plaintiffs the unreasonable burden of
23 having to guess what documents the Defendants did not produce, in contravention
24 of the basic principles of civil discovery and the standard practice in MDLs.
25 Defendants have not taken issue with any *specific* interrogatory or request to
26 produce, choosing instead to issue blanket statements informing the plaintiffs as to
27 what they will not do.

28 Plaintiffs disagree with Defendants that because they have previously

1 produced documents in other litigations in various other jurisdictions, in cases that
2 involved different injuries and different plaintiffs, that they are somehow absolved
3 of their obligations to answer discovery in this MDL.

4 **PLAINTIFFS' ARGUMENT**

5 Plaintiffs oppose Defendants' position on two grounds, the first procedural
6 and the second substantive.

7 First, the purpose of a general ESI order is to address *how* ESI will be
8 produced, not *what* ESI will be produced. Stated another way, this is not the proper
9 vehicle for Defendants to object to certain written discovery. Such a request is
10 better suited for a Motion for Protective Order. However, at present the Court does
11 not even have any specific requests and responses to consider, and thus has no basis
12 on which to rule one way or another on Defendants' request for a protective order,
13 on which Defendants' bear the burden of showing good cause.¹ Instead, Defendants
14 have merely made general references to production in individual cases; the PSC has
15 every intention of working with the Defendants to minimize any repeated
16 discovery, but the Defendants have refused to discuss any overlap in the requests on
17 a request-by-request basis, instead preferring the blanket protective order at bar.

18 Second, Defendants are not relieved of their obligation under the Federal
19 Rules to answer otherwise proper written discovery in MDL 2452. Defendants have
20 cited to no case law, statute, or rule that relieves them of the obligation of
21 responding to written discovery in MDL 2452 by virtue of their prior productions in
22 pancreatitis litigations in other courts. The Rules impose a duty on all parties to
23 avoid unnecessary discovery costs, and the PSC is attempting to do as much; no
24 statute, case, or Rule, however, binds an MDL Court or the PSC to discovery that
25 occurred in other litigation, even if there is overlap in representation between that
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27 ¹ See, e.g., *Foltz v. State Farm Mut. Auto. Ins. Co.*, 331 F.3d 1122, 1130 (9th Cir. 2003) ("A party asserting
28 good cause [for a protective order] bears the burden, for each particular document it seeks to protect, of showing that
specific prejudice or harm will result if no protective order is granted.")

1 litigation and the PSC. All of the Plaintiffs in this litigation have their own rights to
2 discovery, as recognized by the JPML in creating this MDL.

3 Rather than object to specific written discovery requests as they are made,
4 Defendants Amylin and Lilly request that the ESI order in this MDL include
5 provisions to the effect that Defendants' production of documents in other
6 litigations satisfy their obligations in this MDL. Amylin and Lilly ask this Court to
7 order that they are not obligated to amend, alter or re-do its production of these
8 materials. They also ask this Court enter as an order the vague and ambiguous
9 statement that "...to the extent technologically feasible, Plaintiffs will use the
10 previously produced documents and will not request their reproduction under This
11 Order." Plaintiffs oppose making any reference to prior productions in other
12 litigations, for the reasons outlined below.

13 Initially, Plaintiffs have not requested that any Defendant "re-do its
14 production" from other litigation. Rather, Plaintiffs request this case be treated like
15 every other MDL in the country: as a distinct action in which discovery occurs on
16 its own terms. This MDL exists because the Judicial Panel on Multidistrict
17 Litigation found — and the Defendants agreed — that a new centralized action was
18 needed to address the relationship between these four Defendants' products and
19 pancreatic cancer.

20 Defendants request, in essence, that this Court amend the MDL statute and
21 the JPML's order to carve out a new form of subordinated MDL in which the
22 ordinary rules of discovery (and the typical practices in MDLs) do not apply.
23 Defendants contend (i) that this Court is bound by discovery orders entered in a
24 separate consolidated state court action with entirely different plaintiffs and claims,
25 and (ii) that this MDL's PSC is bound by decisions made by individual plaintiffs'
26 counsel in state court cases and pre-MDL federal cases. Such an argument, if
27 accepted, would defeat the very purpose of this MDL, which is to provide for
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1 centralized pre-trial proceedings, and would hold Plaintiffs here to decisions made
2 by attorneys not only outside of this PSC, but outside of this litigation entirely.

3 It is immaterial that Defendants have produced, in response to unspecified
4 document requests in a variety of other litigations (some state, some federal, some
5 consolidated, some individual), documents which could potentially be responsive to
6 requests made here. The real question here, in the context of an ESI protocol order,
7 is the question posed by Fed.R.Civ.P. 26(b)(2)(B): whether Defendants have shown
8 the requested ESI is “not reasonably accessible because of undue burden or cost,”
9 and, if it is not, whether the Plaintiffs have nonetheless “show[n] good cause” for
10 the discovery despite its burden or cost. Plainly, such a determination can only be
11 made on a request-by-request basis, and Defendants have not cited any statute, rule,
12 or precedent in support of their sweeping argument that, because they produced
13 documents in other litigations, they are thus absolved from responding to Plaintiffs’
14 proper ESI discovery requests in this MDL litigation. To the extent Defendants
15 may contend in the future that a particular request can be fully met by way of a
16 production made elsewhere, they may make such argument at that time.²

17 Contrary to Defendants' suggestion, the Biomet opinion supports Plaintiffs'
18 approach. There, Biomet initially collected 19.5 million documents (what the Court
19 called "Square One"), culled down to 3.9 million by way of keyword culling (what
20 the Court called "Square Two"), and then culled further by predictive coding. The
21 Biomet PSC requested the predictive coding begin right after Square One, and the
22 Court denied the request, in part because "The confidence tests Biomet ran as part
23 of its process suggest a comparatively modest number of documents would be
24 found." Here, Amylin and Lilly are not even at Square One, because no broad-

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27 ² Of course, consistent with Fed.R.Civ.P. 26(b)(2)(C)(i), to the extent Plaintiffs can rely on other
28 productions to satisfy their requests, they will do so, but such a determination can only be made as to specific
requests and with specific arguments by the Defendants that the specific discovery at issue can be “obtained from
some other source that is more convenient, less burdensome, or less expensive.”

1 based identification of documents have been done. Rather, in other cases Amylin
2 and Lilly did a small part of Square Two — i.e., they culled with wholly inadequate
3 keywords, to produce in response to unknown requests — and now they would like
4 to preclude Plaintiffs from going any further without first guessing the identity of
5 specific documents in Amylin or Lilly's possession.

6 **CONCLUSION**

7 Plaintiffs request that this Court enters Exhibits 1 and 2 as the orders
8 governing the production of electronically stored information by Amylin and Lilly.
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II. THE DEFENDANTS' POSITION

This motion presents two issues, both of which stem from Plaintiffs' refusal even to acknowledge the millions of pages of documents that Amylin and Lilly have produced to them since December 2012. The first issue is Plaintiffs' demand that Defendants reproduce these millions of pages to make minor and unnecessary changes to the technical specifications. The second is whether, even though members of the PSC negotiated the search terms used for these productions prior to MDL formation, Defendants should now be required to apply still another yet-to-be-determined set of search terms to the same custodial files, when Plaintiffs refuse to explain why they think each new search term is needed.

Amylin and Lilly do not, as Plaintiffs suggest, rely on their existing productions to avoid discovery in this MDL.³ Rather, as their existing productions are technically and substantively complete for the custodians and periods covered, Amylin and Lilly want to move forward. If Plaintiffs disagree, they should tell Amylin and Lilly why additional search terms they want are needed, so that Amylin and Lilly can evaluate Plaintiffs' position concretely. Plaintiffs' demand that Amylin and Lilly commit in the abstract to applying unknown search terms to files that have been robustly searched is not a productive way to advance the litigation.

A. Plaintiffs have had millions pages of documents from Amylin and Lilly since December 2012

Although Plaintiffs' claim their proposed ESI Protocol only governs "how" ESI will be produced, their proposal would dictate "what," requiring that Amylin and Lilly each produce 8 custodial files using new, yet-to-be-agreed upon search terms. Plaintiffs ignore that Lilly and Amylin have produced a year ago (among other documents) custodial files for the following 30 custodians:

³ Plaintiffs' statement that Lilly and Amylin "have refused to discuss any overlap in the requests on a request-by-request basis" is simply not true. Amylin and Lilly have tried to discuss the overlap in search terms, including Plaintiffs' asserted gaps. Until now, Plaintiffs have refused to engage in these discussions.

Amylin

- Diane Beck - Director, Regulatory and Global Safety Operations
- Gary Bloomgren - Senior Director, R&D
- Tom Carpenter - VP, R&D Operations
- Staci Ellis - Director, Regulatory Affairs
- Mark Fineman - Senior Director, R&D Strategic Relations
- Orville Kolterman - Senior VP, R&D
- Dana Lee - Director, Pharmacovigilance
- David Maggs - VP, R&D Strategic Relations,
- Oleg Martynov - Director of Global Safety
- David Parkes - Senior Director, In Vivo Pharmacology
- Ruth Patterson - Director of Medical Writing
- Lisa Porter - VP, R&D ExenatideOne
- Denis Roy - Senior Director, Global Pre-Clinical Lead
- Catherine Schnabel - Associate Director, Medical Affairs
- Kika Teudt - Manager, Regulatory Affairs
- Cheryl Watton - Executive Director, Regulatory Affairs and Global Safety
- Dawn Viveash - VP, Regulatory Affairs and Global Safety

Lilly

- Pam Anderson - Medical Fellow, U.S. Medical Endocrinology
- Dan Braun - Medical Fellow, Global Patient Safety
- Kathryn Broderick - Advisor, Global Regulatory Affairs U.S.
- Andrezj Czarnecki - Deputy Qualified Person for Pharmacovigilance
- Jeffrey Ferguson - Medical Fellow, Global Patient Safety
- Drew Fine - Product Brand Director
- John Fredenburg - Senior Advisor, Global Patient Safety
- John Holcombe - Medical Fellow
- James Malone - Senior Medical Director
- Michael Cobas Meyer - Senior Director, Global Patient Safety
- Rebecca Noel - Research Scientist, Epidemiology
- Donald Therasse - Vice President of Global Patient Safety
- Douglas Wilson - Senior Director of Brand Marketing

In December 2012, Amylin and Lilly produced 4.5 million pages of documents covering the period before December 28, 2009, including custodial documents from the above 30 key safety, regulatory, medical, and marketing custodians involved with Byetta, the IND/NDA, and the adverse event reporting database. This production was made to now-PSC Co-Lead Counsel Ryan Thompson of the Watts Guerra firm, under a protective order which specifically allowed Watts Guerra to share the production with other plaintiffs' counsel. The production was made after Watts Guerra sought pre-suit discovery in Texas for a case they then filed in this Court and which remains pending in this MDL (the

1 “McGerald” action).⁴ These documents were produced in the JCCP, where
2 pancreatic cancer cases have been pending since 2009, and Watts Guerra agreed to
3 the terms and technical specifications for the production. (McGerald Order, Ex. 5.)

4 For the post-2009 period, the Watts Guerra firm and Defendants agreed that
5 Amylin and Lilly would update the custodial productions for six key safety,
6 regulatory and medical custodians through November 2012 using revised search
7 terms. (McGerald Order, Ex. 5.) Watts Guerra proposed the revised terms, and
8 represented that they were developed with input from plaintiffs’ attorneys with
9 pancreatic cancer cases pending in the JCCP, this Court and elsewhere.

10 These agreements were repeated in this Court, beginning with the December
11 12, 2012 ENE Conference, when the Watts Guerra firm and Defendants advised
12 that discovery of Amylin and Lilly was underway pursuant to the McGerald action
13 and search terms. At the Rule 26 Conference on February 4, 2013, now-PSC Co-
14 lead Counsel, Ryan Thompson of Watts Guerra and now-PSC member TJ Preuss of
15 Wagstaff & Cartmell represented that they could speak on behalf of other plaintiffs,
16 including those represented by now-PSC Co-Lead Counsel, Napoli Bern and Tor
17 Hoerman Law.⁵ At the February 25, 2013 Case Management Conference, when
18 this Court inquired about the lack of participation of other plaintiffs’ counsel, Ryan
19 Thompson again represented that he could speak on behalf of all plaintiffs.

20 Relying on these representations, Amylin and Lilly proceeded with a
21 supplemental production. By September 27, 2013, they had produced nearly 2
22 million additional pages of documents using the negotiated search terms.

23 **B. Plaintiffs have not shown why Lilly and Amylin should reprocess**
24 **produced documents to meet Plaintiffs’ preferred specifications.**

25 Amylin and Lilly have agreed to produce new documents according to the

26 ⁴ McGerald v. Amylin Pharmaceuticals, LLC F/K/A/ Amylin Pharmaceuticals, Inc. and Eli Lilly and
27 Company, and Does 1-100, No. 3:13-cv-00747 (S.D. Cal. Mar. 28, 2013).

28 ⁵ In advance of the February 4, 2013, Rule 26 Conference, the parties submitted a Joint Rule 26(f) Report on
January 31, 2013. All three now PSC Co-Lead Counsel are listed as counsel on that Joint Report.

1 plaintiffs' preferred technical specifications, but should not be required to spend
2 tens of thousands of dollars to redo prior productions just to satisfy Plaintiffs'
3 technical preferences, without any compelling reason. The production is in a usable
4 format and technically adequate. These documents have been used by plaintiffs in
5 other courts for years, without complaint. If Plaintiffs have issues with specific
6 documents, they can notify defense counsel. Re-processing the entire production
7 would waste money and time.⁶ If Plaintiffs insist on this, they should bear the cost.

8 **C. Plaintiffs have not shown why Defendants should apply new**
9 **search terms to files covered by the existing production**

10 Lilly and Amylin's prior productions were made using search terms
11 previously agreed to by members of the PSC. Although those terms are sufficient,
12 Defendants are conferring with Plaintiffs on modifications for new productions
13 going forward (i.e., custodians or periods not covered by prior productions). But
14 Amylin and Lilly believe they have provided a complete production from the
15 custodial files that have been searched, and absent any explanation from Plaintiffs
16 why they think specific new terms are necessary to make those productions
17 complete, Lilly and Amylin should not be required to go to great expense to revisit
18 custodians and periods that have been sufficiently covered.

19 Contrary to Plaintiffs' belief, the formation of an MDL where there has been
20 ongoing related litigation does not nullify all pre-MDL discovery, as other courts
21 have recognized. In *In re: Biomet M2a Magnum Hip Implant Prods. Liability*
22 *Litigation* (Ex. 6), the Court denied plaintiffs' request to start review and
23 production over where defendant's production was completed prior to MDL
24 formation and ordered that, if plaintiffs insisted on re-doing the production, it be at
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27 ⁶ Lilly is also in the process of changing production vendors, a process initiated before Plaintiffs' requests
28 arose. Because the data is presently being migrated to a new platform, Lilly would be delayed in accessing it to make
any re-productions.

1 their expense.⁷ The facts here are more favorable to Defendants than in *Biomet*.
2 There, Biomet proceeded with pre-MDL collection and review even though
3 individual PSC members had cautioned Biomet against doing so before MDL
4 formation. *Id.* at *8-*9. Here, Plaintiffs’ Co-Lead Counsel, the Watts Guerra firm,
5 required Amylin and Lilly to make these productions using the negotiated terms.

6 And contrary to Plaintiffs’ assertions, the terms used for the JCCP production
7 were designed specifically to capture cancer-related documents, and “Cancer*” and
8 “Carci*” were included on the list. (See Ex. 7.)

9 Under these circumstances, and without knowing how the search terms that
10 the parties are currently negotiating will ultimately compare to the terms Amylin
11 and Lilly have used to date, there is no basis to require that Amylin and Lilly apply
12 the new search terms to custodial files already covered by the existing production.
13 Plaintiffs have no grounds for claiming that the new, yet-to-be-decided terms will
14 yield more responsive documents (as opposed to a large number of irrelevant
15 documents that will require pointless and expensive review), and Amylin and Lilly
16 cannot fully evaluate the burdens or necessity of applying the new search terms.

17 Plaintiffs’ proposed ESI Order ignores the substantial productions Amylin
18 and Lilly have already made. Amylin and Lilly’s proposed orders, by contrast,
19 account for what has been done, while also leaving room for further discussion and
20 production as discovery proceeds and once the parties have agreed on additional
21 search terms. *See* Exh. 3, ¶C(1)-(2); Exh. 4, ¶C(1). Amylin and Lilly’s proposals
22 will expedite discovery, allowing the parties to build on prior work.

23 **III. PLAINTIFFS’ POSITION IN REPLY**

24 Defendants’ arguments and factual recitations are misleading. For the
25 avoidance of doubt, Plaintiffs note the following:

26 ⁷ 2013 U.S. Dist. LEXIS 84440, No. 3:12-MD-2391 (N.D. Ind. April 18, 2013); *see also* Fed. R. Civ. P.
27 26(b)(2)(B-C) (2013); *In re Nat’l Ass’n of Music Merchs., Musical Instruments & Equip. Antitrust Litig.*, 2011 U.S.
28 Dist. LEXIS 145804, *19 (S.D. Cal. Dec. 19, 2011) (denying plaintiffs’ request for additional search terms after
defendants already produced documents and ordering cost shifting, if plaintiffs insisted on applying additional terms).

1 **1.** The scope of Defendants’ production of documents in the JCCP
2 that Defendants subsequently produced in this action was expressly limited to
3 pancreatitis cases. For this reason, among others, that production is not
4 “substantively complete” for the purpose of this MDL.

5 **2.** The Defendants’ production of documents in the JCCP – which
6 production was expressly limited to pancreatitis cases – includes in large measure
7 documents produced in a form that omits critical metadata. For this reason, that
8 production is not “technically complete” for the purpose of this MDL.

9 **3.** After formation of this MDL, the PSC supplied Defendants with
10 a list of search of terms designed to identify documents discoverable in this MDL.
11 Defendants’ implication that they do not know the PSC’s proposed search terms for
12 this MDL is false.

13 **4.** Prior to the formation of this MDL, in the context of a Texas
14 state court procedure that permits limited pre-suit discovery, Watts Guerra provided
15 Defendants with a non-comprehensive list of search terms regarding one potential
16 pancreatic cancer case.

17 **5.** For the period before December 28, 2009, Defendants’
18 documents have never been subject to a search using search terms provided by any
19 person for the purpose of discovery of documents relevant to pancreatic cancer
20 cases.

21 **6.** For the period between December 28, 2009 and November 12,
22 2012, Defendants’ documents have never been subject to a search based on a
23 comprehensive list of search terms provided by any person for the purpose of
24 discovery of documents relevant to pancreatic cancer cases; rather, at most, such
25 documents were subject to a search based on a limited list of search terms provided
26 under a Texas statute that authorizes limited pre-suit discovery, not broad discovery
27 as contemplated by the Federal Rules of Civil Procedure. Even with the inclusion of
28 two cancer-related terms, namely, “Cancer*” and “Carci*,” the JCCP search terms

were grossly inadequate for the purpose of this MDL.

7. The PSC, acting through Ryan Thompson or otherwise, never agreed to be bound in this MDL to the list of search terms Watts Guerra and Defendants agreed to for the purpose of pre-suit discovery in a Texas proceeding. Nothing supports Defendants' contention that Watts Guerra's agreement with Defendants in a Texas state court pre-suit proceeding that predated formation of this MDL was made with prejudice to the then non-existent PSC's right to conduct full discovery in this MDL.

Respectfully submitted:

Dated: December 20, 2013

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Dated: December 20, 2013

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